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Docket No. 00D-147
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

To Whom It May Concern:

I am writing to provide comments and suggestions for improvement for the Draft Guidance of The Mammography Quality Standards Act Final Regulations Document #4.

Equipment

21 CFR 900.12(b)(8)(i) I do not consider the pneumatic drive of the GE 500T and GE 600T mammography machines to be capable of providing fine compression force control, especially in the cases where the compression force should be eased slightly.

21 CFR 900.12(b)(10) Compliance of the AEC device in all equipment configurations is best demonstrated with the second method (comparing the 4 cm attenuator result across all modes of operation)

Medical Physicist's Annual Survey

21 CFR 900.12(b)(10) A replacement Bucky, even without AEC replacement, has potential for causing significant changes to patient dose and image quality. These changes are more difficult to detect than several of the "repairs" which are listed as needing a MP on-site evaluation.
Specifically, these items in the MP Involvement Table should be changed, as follows:

- Thickness compensation adjustment: should be MP oversight with 30 day verification period; because it is easy for technologist to test (expose a phantom image), and because it is an adjustment – not a repair or replacement, therefore not a regulated item.
- AEC circuit board replacement: should be MP oversight with 30 day verification period; because it is easy for technologist to test (expose a phantom image).
- Collimator Replacement: should be MP oversight with 30 day verification period; because it is not a major repair that would affect patient dose, patient safety or image quality.
- Radiation Output internal adjustment: should be MP oversight with 30 day verification period; because it is easy for technologist to test (expose a phantom image), and because it is an adjustment – not a repair or replacement, therefore not a regulated item.
- High Voltage Generator adjustment: should be MP oversight with 30 day verification period; because it is easy for technologist to test (expose a phantom image), and because it is an adjustment – not a repair or replacement, therefore not a regulated item.
- Film Type change: should be MP oversight with 30 day verification period; because while it is not a major repair, it can certainly affect patient dose and/or image quality.

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Medical Physicist's Annual Survey, continued

In general, all MP oversight issues should have a 30 day verification period, and that verification can be performed by any appropriately trained personnel, i.e. field service engineer, bio-med technician, mammography technologist, junior physicist, etc. Obviously, it is impossible for a MP to perform actual verification tests while providing "MP oversight". The concept is good – when something, anything, changes talk to your physicist, but your MP can almost always provide adequate guidance over the phone.

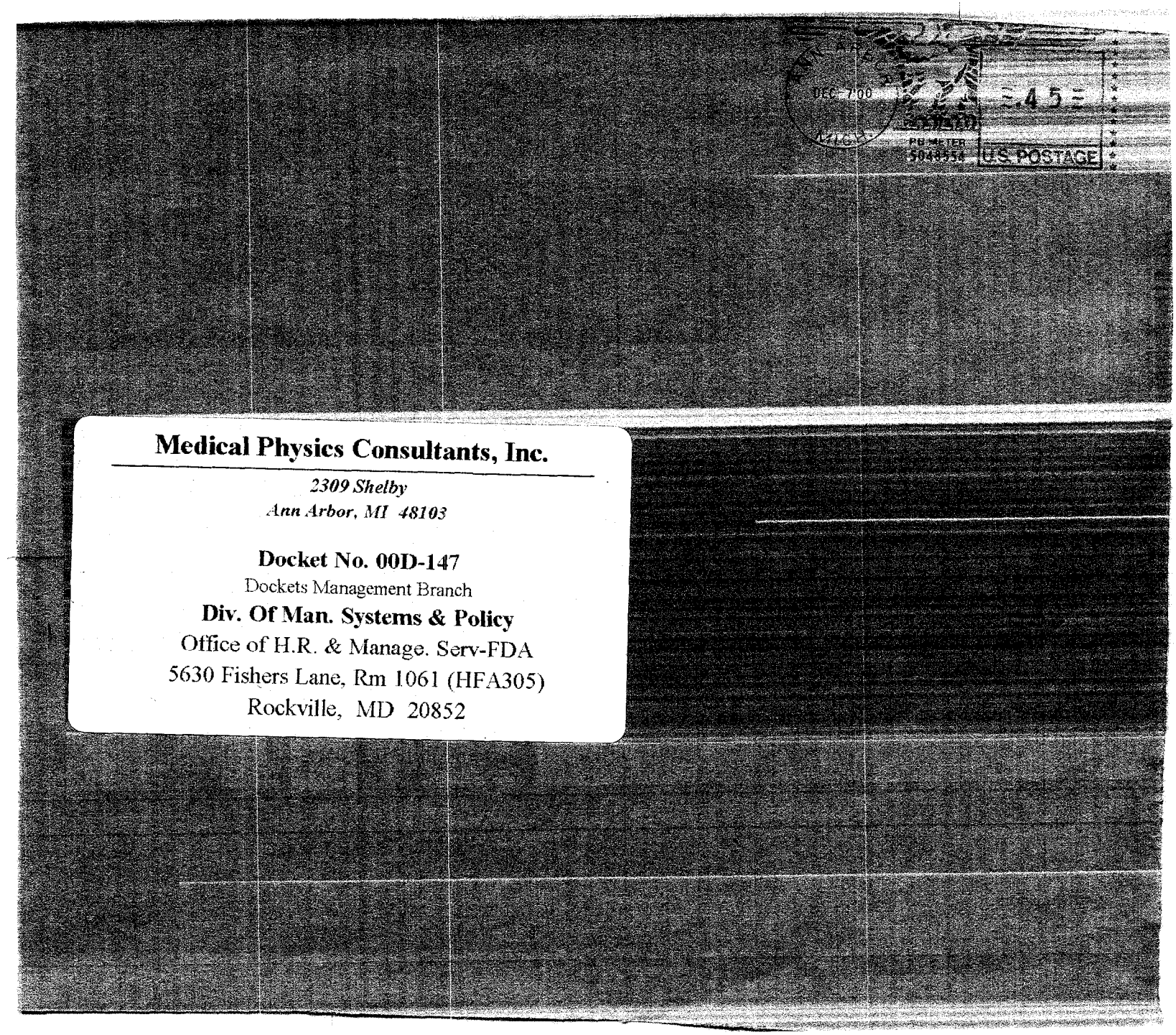
Also, it is inconsistent (and impractical) to have a MP verification test performed to determine 100% compliance before further use of a new or replacement item when that same item, if found to be non-compliant during a routine annual MP survey would have 30 days to be repaired. For example, a new mammography processor is installed and the MP finds guide shoe marks, but otherwise good film processing. The facility should have 30 days to fix the artifact while they are using the processor clinically.

If you have any questions regarding this report or if I may be of any further assistance, please contact me at our office.

Sincerely,

Thomas P. Aufdemberge, M.S.
Diagnostic Radiological Physicist
American Board of Radiology Certified
American Board of Medical Physics Certified

enclosures



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